

December 15, 2014

U.S. Food and Drug Administration Division of Dockets Management, HFA-305 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Docket No. FDA-2011-N-0920 / RIN 0910-AG36) – SUPPLEMENTAL NOTICE

Respectfully submitted by: California Leafy Green Products Handler Marketing Agreement 1521 I Street Sacramento, CA 95814

Introduction

The California Leafy Green Products Handler Marketing Agreement (LGMA) is an instrumentality of the State of California, and was created in 2006 to provide government food safety oversight to the leafy greens industry in California; the LGMA verifies, through government audit, that farmers providing product to LGMA members are implementing accepted good agricultural practices on their farms. The LGMA welcomes the opportunity to comment on the supplemental Preventive Controls Rule published by the FDA on September 26, 2014.

We commend the FDA for its efforts throughout this rulemaking process to communicate with all stakeholders in an effort to create clear and understandable rules for farmers and shippers of fresh produce that protect public health to the extent possible.

We respectfully submit the following comments and suggestions for the Preventive Controls Rule under FSMA:

Farm Definition

The supplemental Preventive Controls Rule improves the definition of *farm*. However, the revised definition still fails to apply to much of modern agriculture in the United States. It has the potential to generate a great deal of confusion about which entities are covered under which parts of the Food Safety Modernization Act (FSMA). Concepts like farms being "under one ownership" and existing "in one general physical location" severely limit modern farm operations in their ability to determine whether or not they comply with the rules.

We recommend that FDA utilize the definition of *farm* proposed by the Produce Marketing Association (PMA) and other organizations in their comments to the public record:



Farm means an establishment where raw agricultural commodities are grown, harvested, packed and/or held, animals are raised (including seafood), or both and have a common, owner, operator(s) or agent in charge and are operated under a common food safety management scheme. The term "farm" includes establishments that, in addition to these activities:

- (i) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and
- (ii) Manufacture/process food, provided that:
 - (A) All food used in such activities is consumed on that farm or another farm under the same ownership; or
 - (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:
 - (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and
 - (2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

Using this definition will improve the Preventive Controls Rule by aligning it more closely with the nature of the agricultural business in the United States today and will eliminate irrelevant concepts (like a farm being under one ownership or existing in one general location). This will make the rule more understandable and logical for farmers, shippers and processors of fresh produce and will clarify that farming and harvest activities are subject to the Produce Rule rather than the Preventive Controls Rule (or by some combination of the two). This definition will also ensure that packing houses are more appropriately regulated based on risk, and not merely by definition of their ownership and location.

Harvest Definition

The Produce and Preventive Controls Rules, as originally proposed, included definitions of *harvest* that would have proved problematic for growers of leafy greens and other types of produce. Many activities that are generally considered part of harvest, including field coring, removing outer leaves, etc. – were originally cited as examples of *processing* and would have compelled coverage under the Preventive Practices Rule. The revised definitions are greatly improved, in that those activities are now listed as examples of harvest. We commend FDA for improving these definitions in the supplemental rules.

The definitions in the two rules are inconsistent in one key aspect, however. As shown below, the Preventive Controls and Produce Rules include identical definitions of *harvest*, with the exception that *Field Coring* is not included in the Produce Rule's list of activities that are considered part of harvest.



<u>Produce Rule</u>: Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food...Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

<u>Preventive Practices Rule</u>: Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food...Gathering, **field coring**, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting (emphasis added).

We assume that the failure to include *Field Coring* in the Produce Rule is an oversight; its inclusion in the Preventive Controls Rule is appropriate and represents, we believe, FDA's intent. Therefore, we suggest that the definition of *harvest* be maintained as is in the Preventive Controls Rule, but that it be corrected in the Produce Rule by adding *Field Coring* to the list of examples of harvest activities. Making this change will improve the Preventive Controls Rule by ensuring that the various FSMA rules are consistent.